angiodynamics

BioFlo Midline

with ENDEXO Technology

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BioFlo Midline

with ENDEXO Technology

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your sales representative. Inspect prior to use to verify that no damage has occurred during shipping.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The *BioFlo** Midline catheter with *ENDEXO** Technology is a radiopaque, polyurethane catheter with luer lock hub(s), polyurethane extension tube(s) and suture wing. The catheter is available in single and dual lumen configurations. The BioFlo Midline is clearly labeled on all available catheter surfaces to identify as a MIDLINE versus a traditional PICC. Maximum power injection flow rates are indicated on the clamp(s) (Figure 1 and Table 2).

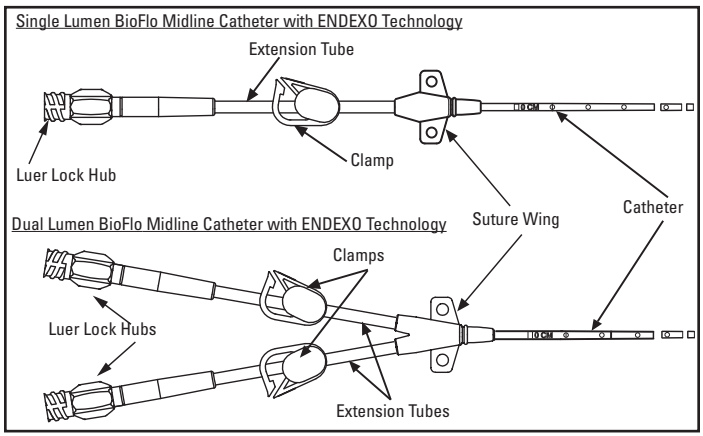

Figure 1. Catheter Configurations

When determining patient selection and catheter diameter, clinicians must consider variations in individual's anatomy and physiology due to size and age (i.e. adult, child, or infant). Appropriate guidance, vein assessment and insertion techniques for BioFlo Midline placement should be employed.

The BioFlo Midline with ENDEXO Technology is provided in multiple packaging configurations, including:

- Maximal Barrier Nursing Kit
- Catheter Kit
- MST Kit with 45 cm Wire

NOTE: MST=Modified Seldinger Technique

ENDEXO technology has been shown to be effective in reducing thrombus accumulation (based on platelet count). Reduction of thrombus accumulation was evaluated using acute in-vitro models. Pre-clinical in-vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation. Endexo technology is a passive, non-active polymer technology intended to reduce catheter-related thrombus accumulation. The device is not intended to treat or eliminate existing thrombus.

INTENDED USE/ INDICATIONS FOR USE

The BioFlo Midline is indicated for short term access (< 30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and the sampling of blood and blood products.

Maximum Power Injection Flow Rate*

- 3F Single Lumen/20 cm -2 mL/sec
- 4F Single Lumen/20 cm - 6 mL/sec
- 5F Single Lumen/20 cm – 6 mL/sec
- 5F Dual Lumen/20 cm - 6 mL/sec

*Refer to table 2

CONTRAINDICATIONS

- Venous thrombosis in any portion of the vein to be catheterized.
- Conditions that impede venous return from the extremity such as paralysis or lymphedema after mastectomy.
- Orthopedic or neurological conditions affecting the extremity.
- Anticipation or presence of dialysis grafts or other intraluminal devices, including pacemakers.
- Hypercoagulopathy unless considerations are made to place the patient on anticoagulation therapy.
- Pre-existing skin surface or subsurface infection at or near the proposed catheter insertion site.
- Anatomical distortion of the veins from surgery, injury or trauma.
- Inadequate antecubital veins.
- Anatomical irregularities (structural or vascular) which may compromise catheter insertion or catheter care procedures.

WARNINGS

Refer to procedural steps for additional warnings. Due to the risk of exposure to blood borne pathogens, care providers must adhere to guidelines for universal blood and body fluid precautions in the care of all patients. Sterile technique must be strictly adhered to during any handling of the device.

- Do not use if package is opened or damaged.
- If using bacteriostatic saline, do not exceed 30 mL in a 24-hour period.
- Do not fully insert catheter up to suture wing.
- Do not use the catheter with chemicals that are incompatible with any of its accessories, as catheter damage may occur.
- Do not re-sheath any needles. Place needles in puncture resistant, leak proof, sharps containers per institutional protocol.
- Do not attempt to trim the catheter with the guidewire or stylet loaded as catheter, stylet, or guidewire may become damaged resulting in patient injury.
- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Power injector's pressure limiting (safety cut-off) feature may not prevent over-pressurization of occluded catheter.
- Exceeding the maximum allowable flow rate (Table 2) may result in catheter failure and/or catheter tip displacement.
- Catheter indication for power injection of contrast media implies the catheter's ability to withstand this procedure, but does not imply appropriateness of this procedure for a particular patient. A trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.
- The maximum pressure of power injectors used with the power injectable BioFlo Midline must not exceed 325 psi (2,240 kPa).
- Prior to loading stylet or guidewire cut catheter to desired length. Do not cut catheter while stylet or guidewire is loaded into catheter as device damage or patient injury may occur.
- Therapies NOT appropriate for BioFlo Midline catheters include those therapies requiring central venous access. Refer to standards of practice and institutional policies.

PRECAUTIONS

Refer to procedural steps for additional precautions.

- Do not advance a guidewire past the level of the axilla.
- Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and re-attempt stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into desired position (zero mark).
- If guidewire must be withdrawn, remove the needle and guidewire as a single unit.
- Carefully read all instructions prior to insertion, care or use.
- Do not use sharp objects to open package as damage to the device may occur.
- Catheter insertion should be performed only by a licensed and qualified healthcare practitioner.
- If catheter and accessories show any sign of damage (crimped, crushed, cut, etc.), do not use.
- If using an introducer sheath other than the one provided (as in Modified Seldinger and Max Barrier kits), verify that the catheter fits easily through the sheath.
- Do not insert the stiff end of the floppy-tipped guidewire into the vein.
- Exercise care when advancing the catheter or guidewire to avoid trauma to the vessel intima. Do not use clamps, toothed or ribbed forceps. Do not use clamps or other instruments with teeth or sharp edges on the catheter or other instruments to advance or position catheter as catheter damage may occur.
- Avoid sharp or acute angles during insertion which may compromise catheter functionality.
- Acetone and polyethylene glycol-containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.
- Catheter replacement may be required if catheter is cut too short.
- Do not use sharp instruments near the extension tubes or catheter shaft.
- Do not suture through any part of the catheter. If using sutures to secure catheter, make sure they do not occlude, puncture, or cut the catheter.
- Following institutional policy, secure catheter externally to prevent catheter movement, migration, damage, kinking or occlusion.
- It is recommended that only Luer lock accessories be used with the BioFlo Midline Catheter with ENDEXO Technology. Repeated over-tightening may reduce hub connector life. Do not use hemostats to secure or remove devices with Luer lock hub connections.
- If resistance is met while attempting to flush catheter, follow institutional protocol for occluded catheters.
- When discarding used accessories, follow institutional protocol.
- Incompatible drug delivery within the same lumen may cause precipitation. Flush catheter lumen following each infusion.
- It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein. The BioFlo Midline Catheter with ENDEXO Technology catheter bench testing included ten (10) power injection cycles.
- Failure to retract the stylet into the catheter prior to catheter insertion may cause vessel damage during insertion procedure.
- Do not use scissors to remove the dressing, as this may possibly cut or damage the catheter.
- Prior to dressing the catheter and access site, inspect both to assure that they are completely dry of isopropyl alcohol or acetone based cleansing agents. To avoid pooling of an agent, do not fully insert catheter up to suture wing.
- Apply a sterile end cap on the catheter hub to prevent contamination when not in use.

- Patient movement may cause catheter tip displacement.
- Do not attempt to repair the catheter. If breaks or leaks are apparent in the catheter, remove the catheter immediately.
- Catheter use, care or removal is to be undertaken only by trained, qualified healthcare provider.
- Use of force to remove the catheter may lead to catheter separation. Hold the catheter distal to the suture wing during removal.
- Patients must be educated regarding the care and maintenance of their BioFlo Midline. The healthcare provider is responsible for this patient instruction.
- Avoid blood pressure measurement or the application of a tourniquet to an arm with an implanted device, since occlusion or other damage to the device may occur.
- Avoid pressure on the inner surface area or axilla of the cannulated arm while using crutches.
- Use of a needle to access the catheter is not recommended. However, if a needle is used, do not use a needle longer than 1.9 cm.

POTENTIAL COMPLICATIONS / ADVERSE EVENTS

- Air Embolism
- Bleeding
- Brachial Plexus or other Nerve Injury
- Catheter Dislodgement
- Catheter Embolism
- Catheter Erosion through Skin/Vessel
- Catheter Fragmentation
- Catheter Malfunction
- Catheter Malposition
- Catheter Migration
- Catheter Occlusion
- Catheter Retraction
- Catheter Rupture
- Death
- Drug or Contrast Medium Precipitate
- Extravasation/Infiltration of Infusate
- Embolism
- Endocarditis
- Exit Site Necrosis
- Fibrin Sheath Formation
- Foreign Body Rejection
- Hematoma
- Hemorrhage
- Hemothorax
- Infection
- Inflammation/Phlebitis
- Intolerance Reaction to Contrast Media
- Intolerance Reaction to Implanted Device
- Malposition
- Nerve Damage
- Pain
- Pleural Effusion
- Pneumothorax
- Pulmonary Embolism
- Renal Compromise
- Sensitivity or Allergy
- Sepsis
- Subintimal Venous or Myocardial Injection
- Thoracic Duct Injury
- Thromboembolism
- Thrombophlebitis
- Vascular Thrombosis
- Vessel Damage
- Vessel Stenosis
- Vessel Tamponade

HOW SUPPLIED

Contents supplied STERILE using an ethylene oxide (EO) process. Store in a cool, dry, dark place. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible. Please see package label for additional storage conditions.

OPERATIONAL INSTRUCTIONS

The BioFlo Midline with ENDEXO Technology is to be inserted, manipulated, and removed only by a qualified, licensed healthcare practitioner. The techniques and procedures described in these instructions do not represent all medically acceptable protocols, nor are they intended as a substitute for a physician's experience and judgment in treating any specific patient. Please refer to the appropriate section based upon configuration selected.

NOTE: Strict aseptic technique must be used during insertion, maintenance and removal procedures. Prior to use, carefully examine the product to verify that it has not expired and the sterile package has not been damaged in shipment.

PRECAUTION: Do not use sharp objects to open package.

Table 1. Catheter Specifications

French Size (mm) (Outer Diameter)	Lumens	Lumen Gauge[1]	Catheter Length (cm)	Minimum Gravity Flow Rate (Water) (mL/hr)	Lumen Size (mm)	Priming Volume (mL)
3F (1.02)	1	20.0	20	512	0.6	0.43
4F (1.40)	1	17.0	20	1928	0.9	0.52
5F (1.68)	1	15.5	20	2280	1.1	0.57
5F (1.73)	2	17.5[2]	20	1524	0.8/0.8	0.60

1 Maximum guidewire compatibility is 0.018 in. (0.46 mm).
2 Both lumens.

INSTRUCTIONS FOR USE
CATHETER INSERTION DIRECTIONS

Patient Preparation

1. If placing catheter at patient bedside, apply tourniquet to upper arm. Select a vein based on patient assessment. Common veins used for insertion include the Basilic, Brachials and Cephalic. Release tourniquet.
2. Prepare sterile field and supplies.
3. Prepare insertion site and surrounding area with an acceptable topical antimicrobial cleansing agent according to institutional protocol, policies and procedures.

Venous Access

4. Access vein using the appropriate method below.

Using Guidewire

a. Insert introducer needle, bevel up, into selected vein and confirm vessel entry.

b. Insert soft or guiding tip of the guidewire through the needle and into the vein to the desired position based on clinical practice guidelines and standards or institutional policy and procedure.

NOTE: If using hydrophilic guidewire, fill the wire holder (hoop) or bathe the guidewire with sterile normal saline for injection to ensure activation of the hydrophilic coating prior to the procedure. This may need to be repeated during the procedure by gently flushing the catheter with sterile normal saline solution for injection through the supplied flush assembly with the guidewire in place.

c. Recommended tip location is at or below the axillary line.

PRECAUTION: If guidewire must be withdrawn, remove the needle and guidewire as a single unit.

d. Gently withdraw safety needle from guidewire while holding guidewire in place.

Safety Needle Use

i. To activate safety mechanism, hold safety handle in one hand and rotate flashback chamber counter-clockwise.

ii. Pull back on flashback chamber until needle tip disappears into safety handle and locks securely into needle handle (indicated by audible click and feel).

iii. Verify needle tip is securely locked inside safety handle by pushing flashback chamber forward while holding safety handle. Repeat prior step, if necessary.

e. Discard needle per institutional protocol

Access without using guidewire

a. Select peelable sheath safety introducer needle.

b. Insert peelable sheath safety introducer needle per manufacturer's instructions for use.

NOTE: Ensure sheath lies within vessel.

c. Release tourniquet.

d. Retract needle half way out of peelable sheath, maintaining sheath position.

e. Hold peelable sheath in place, and remove safety needle per manufacturer's instructions for use. Discard according to institutional protocol.

NOTE: Do not reinsert introducer needle into peelable sheath, as this may cause damage to sheath.

Catheter Preparation

NOTE: Catheter preparation may occur prior to venous access, if catheter is being placed at patient bedside.

5. Determine catheter length.

NOTE: The BioFlo Midline catheter tip location should be at or below the axillary line.

a. Bedside Placement: Position patient with arm extended outward from body at a 90-degree angle, or as tolerated. Measure distance along vein track between selected insertion site and the desired catheter tip location.

6. Cut catheter to length, using previous measurement.

NOTE: Cut catheter tip square. Inspect cut surfaces to ensure there is no loose material or rough edges.

7. Attach flush assembly to catheter hub. Ensure locking collar is in open position (Figure 2).

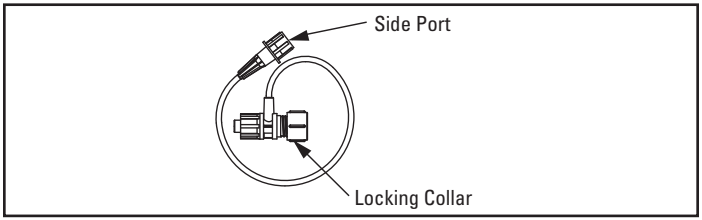

Figure 2. Flush Assemblies

NOTE: When inserting a dual lumen catheter either lumen may be used for stylet placement.

8. Draw 10 mL sterile normal saline into syringe (unless already supplied pre-filled), remove cap on side port of flush assembly, and attach syringe.

9. While covering locking collar opening with finger to prevent fluid loss, prime flush assembly and catheter.

NOTE: For multi lumen catheters, be sure to prime each lumen prior to insertion, clamping unused lumen(s) after it is primed.

10. If stylet is used (recommended for all techniques except for Seldinger technique), advance stylet slowly through flush assembly locking collar into catheter until tip of stylet extends beyond end of catheter. Continue to inject sterile normal saline, as needed, to assist in advancement.

11. Retract stylet back to a position at least one cm within the catheter (Figure 3).

Figure 3. Stylet Position within Catheter

PRECAUTION: Failure to retract stylet into catheter prior to catheter insertion may cause vessel damage during insertion procedure.

12. Turn flush assembly locking collar clockwise to secure stylet in place.

WARNING: Do not cut stylet or guidewire.

PRECAUTION: Do not reinsert stylet into catheter, as damage to catheter and vein may result.

PRECAUTION: Do not apply any type of clamp on catheter or extension tube while stylet is inside catheter. Stylet may become kinked and damage catheter, resulting in leakage or fracture of catheter.

13. Remove syringe from flush assembly and place cap on side port.

Catheter Placement Using Guidewire

a. Alongside guidewire, nick insertion site with safety scalpel. To use safety scalpel, depress top button on protective shield, and retract to rear locked position. Once nick is made, depress top button again and advance to forward locked position at lock indicator line.

b. Advance peelable sheath/dilator assembly over guidewire. Using a slight twisting motion, advance assembly into the vein.

c. Seldinger technique: Withdraw the dilator, leaving the sheath and guidewire in place.

   Modified technique: Withdraw dilator and guidewire together, leaving peelable sheath in place. Cover opening to prevent blood loss and/or air embolism.

14. If placing catheter at patient bedside turn patient's head toward insertion side with chin to shoulder.
15. Slowly and incrementally, insert catheter assembly through the peelable sheath to desired tip location.

NOTE: If inserting multi lumen catheter, ensure that extension tube(s) not being used is clamped.

NOTE: If practicing Seldinger technique, wet the exposed segment of the guidewire with saline and thread catheter over guidewire first.

16. Holding catheter steady, slowly withdraw peelable sheath from insertion site.
17. Grasp wings of sheath firmly, and pull apart applying equal pressure to both wings - peel the sheath away from the catheter using a forward motion. Discard according to institutional protocol.
18. Slowly advance remaining catheter into vein until "0" mark on catheter is at insertion site. Do not fully insert catheter to suture wing.
19. Loosen flush assembly from catheter hub and withdraw, with stylet or guidewire, while holding suture wing in place. Discard according to institutional protocol.
20. Once catheter is inserted, aspirate gently with syringe attached to flush assembly side port and observe for blood return. Detach and discard according to institutional protocol.

PRECAUTION: Do not reinsert stylet into catheter, as damage to catheter or vein may occur.

21. Close catheter clamp.
22. See FLUSHING AND HEPARINIZATION and CATHETER STABILIZATION sections for next steps.

FLUSHING AND HEPARINIZATION

1. Attach syringe to hub, open clamp, and aspirate blood.
2. Close clamp, detach syringe and discard according to institutional protocol.
3. Attach syringe filled with 10 mL sterile normal saline, open clamp, and flush lumen, using a "pulse" or "stop/start" technique.

NOTE: If flushing after a power injection, use 20 mL sterile normal saline.

4. Close clamp, detach syringe and discard according to institutional protocol.
5. Draw heparinized saline into syringe, and attach to hub.
6. Open clamp, and inject amount equal to or greater than priming volume into lumen (see Table 1).
7. Maintaining positive pressure on syringe, close clamp, detach syringe and discard.
8. Repeat for second lumen, if necessary.

NOTE: Never leave catheter uncapped.

NOTE: Flush catheter after every use. When not in use, flush at least every 12 hours, or according to institutional protocol to maintain patency.

CATHETER STABILIZATION

1. Prepare stabilization site with alcohol and remove betadine, if present.
2. Apply skin prep solution for enhanced adherence and skin protection. Allow skin prep solution to completely dry.
3. Slide device under suture wing. Slide one suture hole over a post, then slide that post and suture wing toward opposite side until second suture hole easily fits over second post.
4. Close lids over posts to secure catheter.
5. Peel away paper backing and place on skin.
6. Apply adhesive strip at or near insertion site.

CONTRAINDICATION: Patients with known tape or adhesive allergies.

PRECAUTION: Do not use where loss of adherence could occur, such as with a confused patient, unattended access device, diaphoretic or non-adherent skin.

PRECAUTION: Minimize catheter manipulation during application and removal.

NOTE: Monitor stabilization device daily. Replace at least every seven days.

POWER INJECTION

Table 2. Power Injection Specifications

French Size (mm) (Outer Diameter)	Lumens	Catheter Length (cm)	Maximum Flow Rate for 11.8 cP CT Contrast (ml/sec) [1]	Maximum Catheter Pressure at Maximum Flow Rate (psi [1,2] (kPa))	Maximum Static Burst Pressure Post Injection (psi [3] (kPa))
3F (1.02)	1	20	2	168 (1158)	299 (2062)
4F (1.40)	1	20	6	181 (1248)	309 (2128)
5F (1.68)	1	20	6	153 (1055)	302 (2085)
5F (1.73)	2	20	6	172 (1186)	251 (1733)

1 Testing was conducted using contrast with viscosity of 11.8 centipoise (cP), measured at body temperature (37°C) with injector set at 325 psi (2,240 kPa). Data represent approximate flow capabilities of power injection of contrast media.
2 Internal catheter pressure data point observed during power injection testing.
3 Burst pressure is the static burst pressure failure point of the catheter after completion of 10 power injection cycles.

WARNING: During power injection testing catheter pressures did not exceed those outlined in Table 2.

WARNING: During static burst pressure testing, catheter failure was recorded as detailed in Table 2.

WARNING: Exceeding maximum allowable flow rate (Table 2) may result in catheter failure and/or catheter tip displacement.

1. Verify power injector is appropriately programmed and does not exceed catheter flow rate limit (see Table 2).
2. Warm contrast to body temperature (37°C).

   WARNING: Failure to warm contrast media to body temperature prior to power injection study may result in catheter failure.

3. Inspect catheter for damage.
4. Attach syringe, open clamp, and aspirate amount greater than priming volume of catheter, or until blood return (Table 1). Close clamp, and remove and discard used syringe according to institutional protocol.
5. Attach syringe filled with 10 mL sterile normal saline, open clamp, and vigorously flush lumen.
6. Close clamp, and detach syringe and discard according to institutional protocol.

   WARNING: Failure to ensure catheter patency prior to power injection studies may result in catheter failure.

   PRECAUTION: If a needleless connector is attached to catheter hub, first ensure that it will sustain power injection.

7. Attach power injector to selected lumen hub per manufacturer's recommendations, and open clamp.
8. Complete power injection study taking care not to exceed maximum flow rate limit (Table 2), and close clamp.

   PRECAUTION: It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein. The BioFlo Midline with ENDEXO Technology catheter testing included ten (10) power injection cycles.

9. Disconnect the power injector.
10. Refer to FLUSHING AND HEPARINIZATION section.

CATHETER MAINTENANCE

It is recommended that institutional protocols be followed for all aspects of catheter care, use and maintenance. The following care, use and maintenance information is not intended as a substitute for institutional protocol, but rather, to describe guidelines and recommendations that can be used successfully with the BioFlo Midline with ENDEXO Technology.

GENERAL CATHETER CARE AND USE

- Use aseptic technique during catheter care and use.
- Use Standard and Universal Precautions during catheter care procedures.
- Never leave catheter uncapped.
- Do not use clamps, or instruments with teeth or sharp edges on the catheter, as catheter damage may occur.

CARE OF INSERTION SITE AND DRESSING

- Examine insertion site, including catheter stabilization device, routinely and with each dressing change, for complications.
- Follow institutional protocol for dressing change. It is recommended that dressings be changed weekly and as necessary.
- To maintain unobstructed flow, make sure there are no kinks in catheter or IV tubing.

  WARNING: Prior to dressing catheter and access site, inspect both to assure they are completely dry of isopropyl alcohol-based cleansing agents.

- A sterile, occlusive dressing covering the entire insertion site, suture wing and at least 2.5 cm of the extension tube is recommended.
- All efforts are to be made to keep insertion site and dressing clean, dry and intact.

DRESSING REMOVAL

- Stabilize catheter and Luer lock hub during dressing removal to prevent accidental dislodgment.
- Separate dressing away from Luer lock hub and toward insertion site. As you separate, keep any tape and dressing close to patient's arm to avoid dislodging catheter or sutures.

ASSESSING CATHETER INTEGRITY

Assess catheter integrity before any injection/infusion by completing the following steps:

- Examine and palpate catheter tract and insertion site for complications.
- Using a 10 mL syringe, aspirate slowly for blood return. Difficulty in withdrawing blood may indicate catheter compression, malposition, and/or obstruction. Discard syringe according to institutional protocol.
- Using second 10 mL syringe, flush catheter with 10 mL of sterile normal saline to clear catheter.

NOTE: If catheter integrity is questioned as a result of any of the above steps, do not use catheter without further inquiry and resolution of the problem.

BLOOD SAMPLING

1. Stop administration of infusates.
2. Using aseptic technique, swab catheter hub and allow to air dry.
3. Flush the selected lumen with 10 mL of sterile normal saline.
4. Use syringe to aspirate small amount of blood and fluid (3-5 mL minimum) to verify patency. Discard syringe according to institutional protocol.
5. Using second syringe, slowly withdraw specimen, and close clamp.
6. Refer to FLUSHING AND HEPARINIZATION section.
7. Transfer specimens as per institutional protocol.

MANAGEMENT OF LUMEN OCCLUSION

The lumens of BioFlo Midlines may infrequently become obstructed. Lumen obstruction is usually evident by failure to aspirate or infuse through the lumen or inadequate flow and/or high resistance pressures during aspiration and/or infusion. The causes may include but not limited to catheter tip malposition, catheter kink, or clot. One of the following may resolve the obstruction:

- Verify there is no kinked tubing in the catheter section external to the body.
- Reposition the patient.
- Have the patient cough.
- Provided there is no resistance with aspiration, flush the catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall. Use a 10 mL or larger syringe.

PRECAUTION: Never forcibly flush an obstructed lumen. If any lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, consult institutional protocol for management of thrombosis.

CATHETER REPAIR

In the event that the catheter is accidentally torn or broken, it is recommended that the catheter be replaced.

CATHETER REMOVAL

Catheter removal is per the discretion of the physician in regards to the patient's therapy regimen.

1. Position patient upright with arm at 45-degree angle outward from body. Maintain insertion site below level of heart.
2. See DRESSING REMOVAL section.
3. Open catheter stabilization device retainer lids and remove catheter from retainer.

NOTE: It is preferred to use aseptic technique for the following steps.

4. To remove catheter, grasp catheter between suture wing and insertion site and remove slowly, in small increments, keeping catheter parallel to skin surface. Do not grasp Luer lock hub to remove catheter, as catheter damage may occur.
5. If resistance is still met, follow institutional protocol for the management of difficult-to-remove catheters.
6. To verify that entire catheter has been removed, measure and compare catheter length with initial length recorded at time of insertion.
7. Apply generous amount of alcohol to loosen edges of catheter stabilization device. While lifting adhesive pad, gently stroke undersurface of pad with alcohol to dissolve adhesive.
8. Following removal of catheter, cover insertion site with occlusive dressing for at least 24 hours.

WARRANTY

Navilyst Medical, Inc. warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Navilyst Medical's control directly affect the instrument and the results obtained from its use. Navilyst Medical's obligation under this warranty is limited to the repair or replacement of this instrument and Navilyst Medical shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Navilyst Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Navilyst Medical assumes no liability with respect to instruments reused, reprocessed, resterilized, modified or altered in any way, and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such.**

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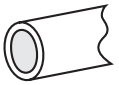
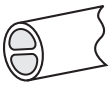


Single Lumen



Dual Lumen

Legal Manufacturer

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